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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,215	12/19/2000	Qi Jia	UNI.15/D	7672

25871 7590 11/17/2003

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/17/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/741,215

Applicant(s)

JIA ET AL.

Examiner

Patricia A Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15, 16, 19, 23 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15-16, 19, 23 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on September 5, 2003 has been entered. Subsequently, the Amendment filed After final rejection on 8/6/03 has hereby been entered.

Claims 13, 15-16, 19, 23 and 26 remain pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15-16, 19, 23 and 26 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It has been recently discovered that the phrase 'neutralization and concentration of the neutralized extract' is new matter. The reason this phrase is new matter is because it does not appear that Applicant disclosed these method steps for the purification of the alkaloid as presented in claim 1. Specifically, the purification of Magnoflorine or Laurifoline were extracted without any neutralization step, and while other species of alkaloids may have been prepared with the method of claim 1, it does not appear that Applicant contemplated neutralization and concentration of the crude extract prior to purification with regard to this particular embodiment.

Also, the phrase 'purification of said extract by a chromatographic method' (emphasis added) is also deemed new matter within the context of the claim which now recites 'consisting of'. Although claim 13 states 'wherein said chromatographic method is selected from the group consisting of.....or a combination of two or more of these methods', it does not appear that Applicant was in possession of the entire scope of the claimed invention which clearly states that only one chromatographic method such as ultra-filtration needs to be used for purification. Specifically, the purification of Magnoflorine or Laurifoline Applicant as taught in the Instant specification, were purified on more than one column; specifically: MPLC (CG-161), reverse phase HPLC and LH-20 for Magnoflorine, and an extra reverse phase column for Laurifoline. Thus, it does

not appear that Applicant taught or eluded to any method for extracting Magnoflorine or Laurifoline with only one type of chromatography method such as ultra-filtration in the Specification as originally filed, and therefore this language is considered New Matter.

Because claims 15-16, 19, 23 and 26 depend upon claim 13, these claims also recite new matter and are rejected for the same reasoning as set forth *supra*.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 15-16, 19, 23 and 26 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites 'consisting of'. Although it is clear what the term 'consisting of' means typically, it is not understood what it means within the context of this claim. The reason this claim is now found indefinite, is that the metes and bounds of consisting of the steps of (a), (b) and (c) are not clearly delineated. For example, purification by a chromatographic method is a broad concept which typically encompasses dissolving an analyte prior to loading onto the column, eluting into fraction quantities, choosing the fraction of interest and removal of the elution solvent (and of course this routine is repeated for multiple chromatography runs). Further, the term 'extraction' is also a

broad concept. Does Applicant intend to exclude multiple extraction steps or heating steps for example? Therefore, it cannot be absolutely determined what Applicant intends to exclude from the claim by the recitation of 'consisting of'. Further, the phrase 'neutralization and concentration of the neutralized extract' is now found confusing. It appears that a critical element may be missing between steps (a) and (b); why does the solvent need to be neutralized? It appears that an acid or base was added, but not specifically recited in the claim. Clarification is necessary.

In light of the new limitation which reads 'consisting of' the prior art rejections have been removed. However, upon the deletion of the New matter in claim 13, a new art rejection may be in order.

Although Applicant's arguments are moot in light of the removal of the prior art reference, the Examiner would like to answer an embodiment of Applicant's principal argument in order to better explain the Examiner's reasoning which may better facilitate prosecution on the case. Applicant argues: "Contrary to the Examiner's assertion, absorption phase chromatography, typically performed on nonbonded silica gel containing Si-OH functional groups, is quite distinct from ion-exchange chromatography, which is performed on a stationary phase that contains fixed ionic charges. This fact is well documented and would be well known to those skilled in the art" (p.7-Arguments). The Examiner concedes on this point. The reference did not specifically teach that the silica gel was used, in this particular instance, as an ion exchange column. However,

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the Examiner had previously also mentioned that silica gel is a type of size exclusion matrix. The Examiner has provided an excerpt from R.P.W. Scott, The Mechanism of Chromatographic Retention: "All stationary phases based on silica gel exhibit exclusion properties". Scott goes on to explain the amorphous and porous characteristics of silica gel which imparts these exclusion properties (one page, Laboratory Talk web site). Therefore, it remains the opinion of the examiner that silica gel does perform size exclusion based upon its physical characteristics.

It is noted that the prior art references were dropped because a method was not clearly found which only included the steps as recited in claim 1. However, as indicated *supra*, removal of the new matter may result in a new prior art rejection. It is noted that the procedure for purifying Magnnoflorine and Laurifoline as taught on p.14 of the Instant specification is free of the art.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (703) 308-1189. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (703) 306-3220. The fax phone

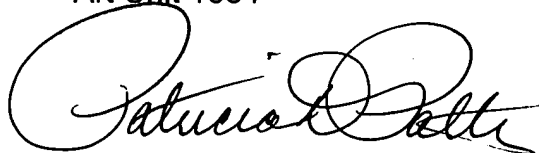
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number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

11/06/03

Patricia A Patten
Examiner
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A handwritten signature in black ink, appearing to read "Patricia A. Patten", with a large, stylized initial "P" and a long, sweeping underline.

**PATRICIA PATTEN
PATENT EXAMINER**